CHEMBIO DIAGNOSTICS, INC.

**NASDAQ: CEMI**


# RAPID tests for EARLIER treatments

**Investor Presentation**

**January 2013**

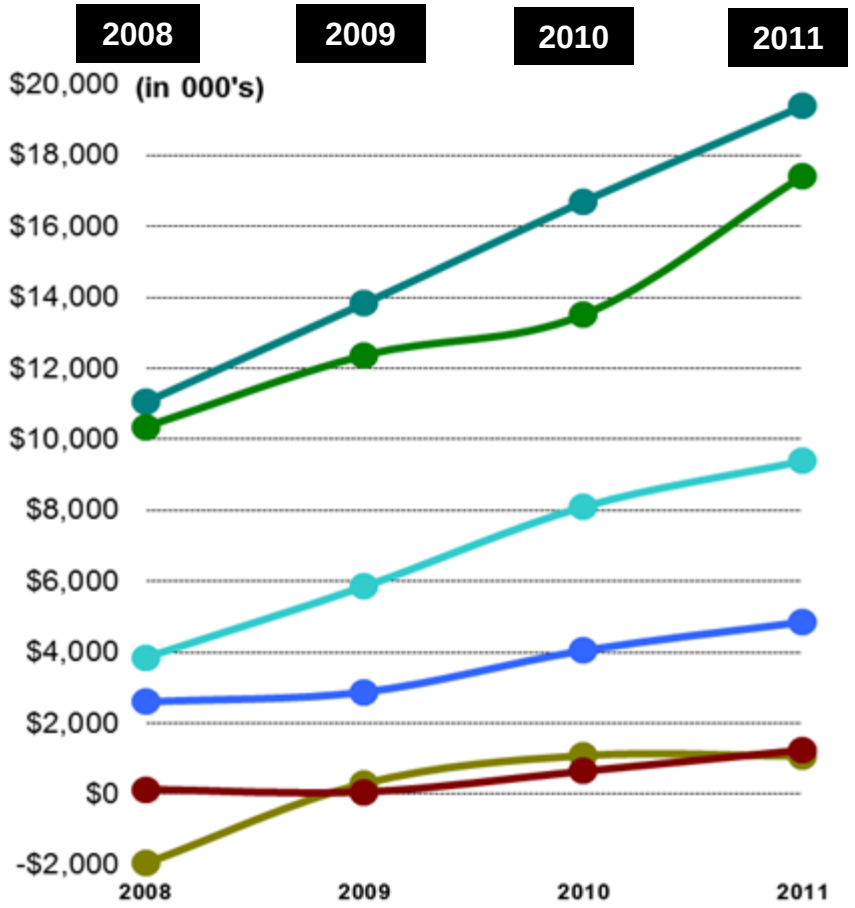
# Forward-Looking Statements

Statements contained herein that are not historical facts are forward-looking statements within the meaning of the Securities Act of 1933, as amended. Those statements include statements regarding the intent, belief or current expectations of Chembio and its management. Such statements reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events, or performance may differ materially from the above forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to, Chembio's ability to develop, manufacture, market and finance new products and the demand for Chembio's products. Chembio undertakes no obligation to publicly update these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Other factors that may impact Chembio's success are more fully disclosed in Chembio's most recent public filings with the U.S. Securities and Exchange Commission.

# Investment Summary

- Develops, Manufactures & Markets Point-of-Care Diagnostic Tests (POCTs) Using Company's Patented DPP® Platform Technology
- Current Revenues Primarily from HIV & Syphilis POCTs Sold Globally
- Profitable FY2009-2011 & 9 Months of 2012
  - Anticipate Strong Fourth Quarter 2012 Sales
- Partnered with Leading License & Distribution Partners in U.S. & South America
- Recent FDA Approval of Oral Fluid HIV Test
  - First DPP® test approved by FDA
- Strong Pipeline of POCTs
- Experienced Management Team

# Selected Financial Data FY2008 – 2011 & 9 Mos 2012; Anticipate Reporting Record Revenues Again for FY2012

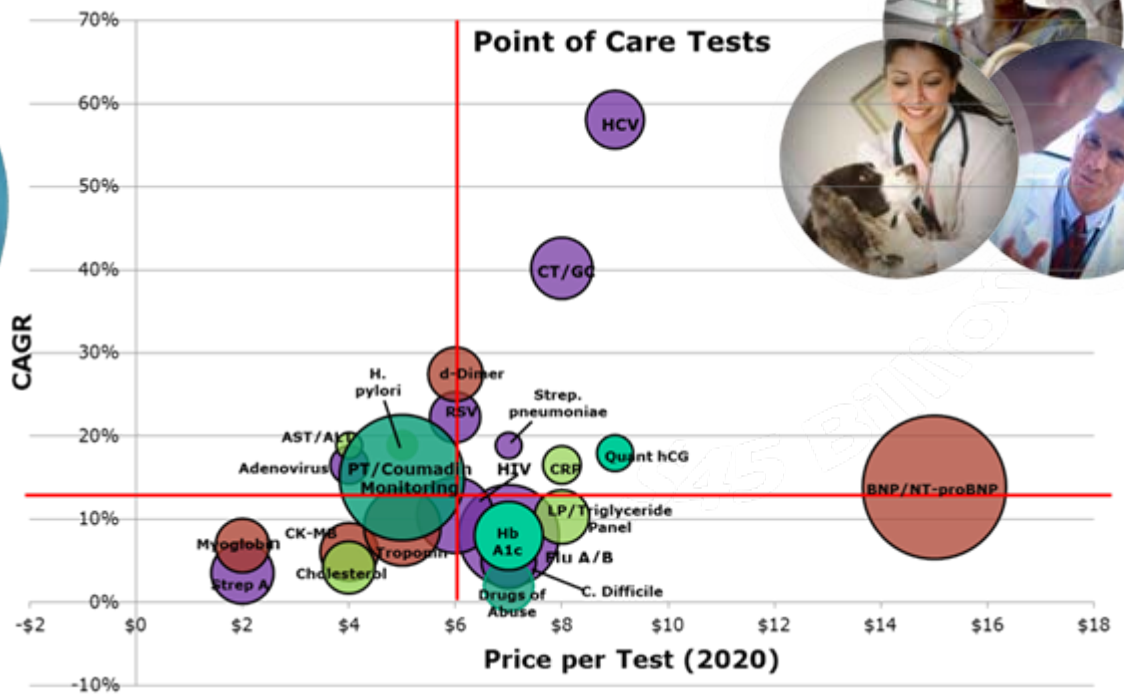



| | 2011 | 2012 9 Mos. |
|---|---|---|
| Total Revenue | $19,413 | $17,744 |
| Product Revenue | $17,422 | $16,919 |
| Gross Profit | $9,291 | $7,632 |
| R&D Expense Incl. Clin. Trials* | $4,853 | $3,364 |
| Clinical Trials | $1,244 | $663 |
| Pre-Tax Income | $1,003 | $745 |

* Non-recurring 2010 $1.5MM R&D Credit from the Affordable Care Act – excluded from 2010 R&D Exp. & 2010 Pre-Tax Income

# POCTs - A Growing Global Market

## *Converting Lab Tests to POC and Creating New Markets*




**Est. $10B Global POCT Market ; >$45B Total In-Vitro DX Market**



CHEMBIO

# Chembio Target POCT Markets – 2013-2016

- HIV
  - Significant Position with Lateral Flow Tests in US and Globally
  - DPP® Oral Fluid HIV Test FDA Approved 12/19/2012
  - $75MM US Market; $250MM Global Donor-Funded Market; Self-Testing Over-the-Counter Potential
- Syphilis
  - High Rates of Co-Infection with HIV, No POCT in U.S.
  - Two DPP® Products in Pipeline – Potential $75MM Market
- Hepatitis-C
  - Potential Baby Boomer Testing Cohort Represents Potential 80MM 1x Testing Opportunity; New Therapeutics
  - DPP® Product in development
- Other New POCT Markets TBD in the US & Globally

# New Product Commercialization Estimated Timelines – U.S. & International

## 2013

- DPP® Oral Fluid and Blood Rapid HIV Assay CLIA Waiver & Launch
- International
  - HIV-Syphilis

## 2014

- DPP® Syphilis Screen/Confirm
- DPP® HIV-Syphilis Assay
- International
  - HIV OTC
  - HCV

## 2015-2016

- DPP® HCV Assay*
- HIV OTC*
- 4th Gen. &/or Assays with New Detection and Reader Technologies

***Subject to ongoing market assessment***

**Complementing Strong US and Global Revenue Base**

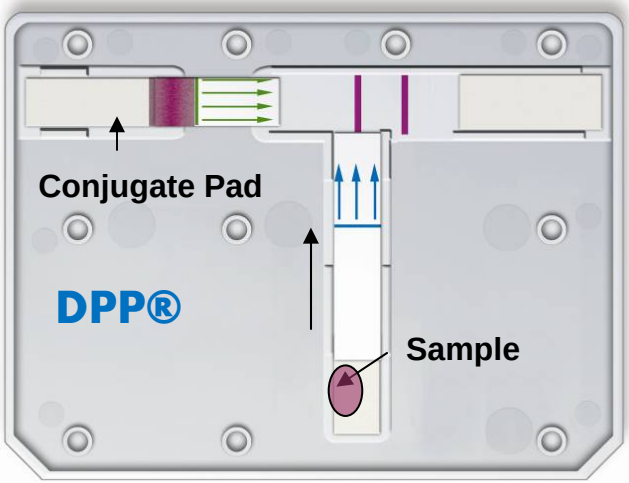


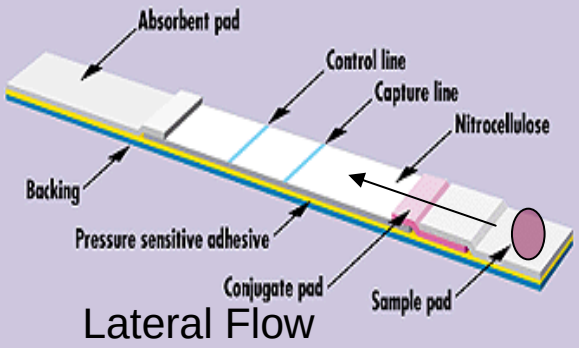
CHEMBIO

# Chembio's Patented Technology Platforms:
## *In-Licensed Lateral Flow and Patented Dual Path Platform (DPP®)*

- **DPP® - A Patented POCT Platform Technology**
  - Enables Improved Performance, Multiplexing, Sample Control, Line Clearance, Detection Systems


  - Validated with Numerous Partners, Regulatory Agencies
  - Patents Issued in US and Multiple Countries
  - Continuing Prosecution & Expansion of IP



# Revenue Primarily from 3 FDA-Approved Rapid HIV Tests Sold Globally

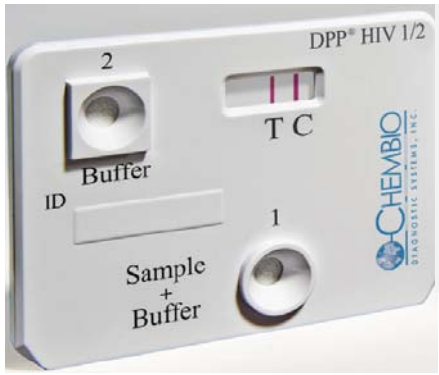
PEPFAR

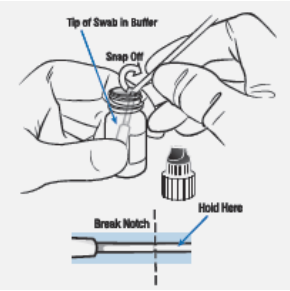
The Global Fund To Fight AIDS, Tuberculosis and Malaria | 10 YEARS OF IMPACT


**HIV STAT PAK**
**LATERAL FLOW TEST**
***Marketed in US by Alere as Clearview HIV 1/2 STAT PAK***

Alere


**CHEMBIO SURE CHECK HIV LATERAL FLOW TEST**
***Marketed in US by Alere as Clearview Complete***




**DPP® HIV 1/2 ASSAY**
**For use with oral fluid or blood samples**
**Approved by FDA Dec. 2012**
***Launched 2011 in Brazil; Anticipated 2H 2013 in US***

- **Large International Screening Programs (PEPFAR) - Distribution and Direct Sales**
- **Lateral Flow Products in US Exclusive through Alere**
- **DPP® FDA Approved Dec. 2012**
  - **Marketing Options - Direct Sales and/or Distribution**



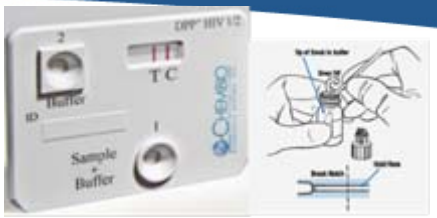
CHEMBIO

# Collaboration with FIOCRUZ in Brazil


- **Oswaldo Cruz Foundation (FIOCRUZ)**
  - Key Supplier to Brazilian Federal Ministry of Health
  - Aggregate of $23MM in DPP® Tech. Transfer Contracts
  - Approximately 50% Completed 2011-2012
- **Potential New Products & Collaborations in Brazil with FIOCRUZ & Others**
  - Public Market
  - Private Market

# DPP HIV®1/2 Assay: FDA-Approved December, 2012

## Clinical Trial Performance Data on Finger Stick Whole Blood and Oral Fluid




**Diagnostic Accuracy of the POC DPP HIV 1/2 Assay**

| Country<br>*Specimen Type* | Reference Positive | No. of Positive | Sensitivity, % (95% CI) | Reference Negative | No. of Negative | Specificity, % (95% CI) |
|---|---|---|---|---|---|---|
| Mozambique | | | | | | |
| *Oral Fluid* | 516 | 516 | 100 (99.3-100.0) | 1157 | 1157 | 100 (99.7-100) |
| Nigeria | | | | | | |
| *Oral Fluid* | 225 | 225 | 100 (98.4-100.0) | 420 | 420 | 100 (99.1-100.0) |
| *Fingerstick Whole Blood* | 225 | 225 | 100 (98.4-100.0) | 418 | 418 | 100 (99.1-100.0) |
| United States | | | | | | |
| *Oral Fluid* | 963 | 953 | 98.9 (98.1-99.5) | 1816 | 1815 | 99.9 (99.7-99.9) |
| *Fingerstick Whole Blod* | 963 | 962 | 99.9 (99.4-99.9) | 1815 | 1815 | 100 (99.8-100.0) |

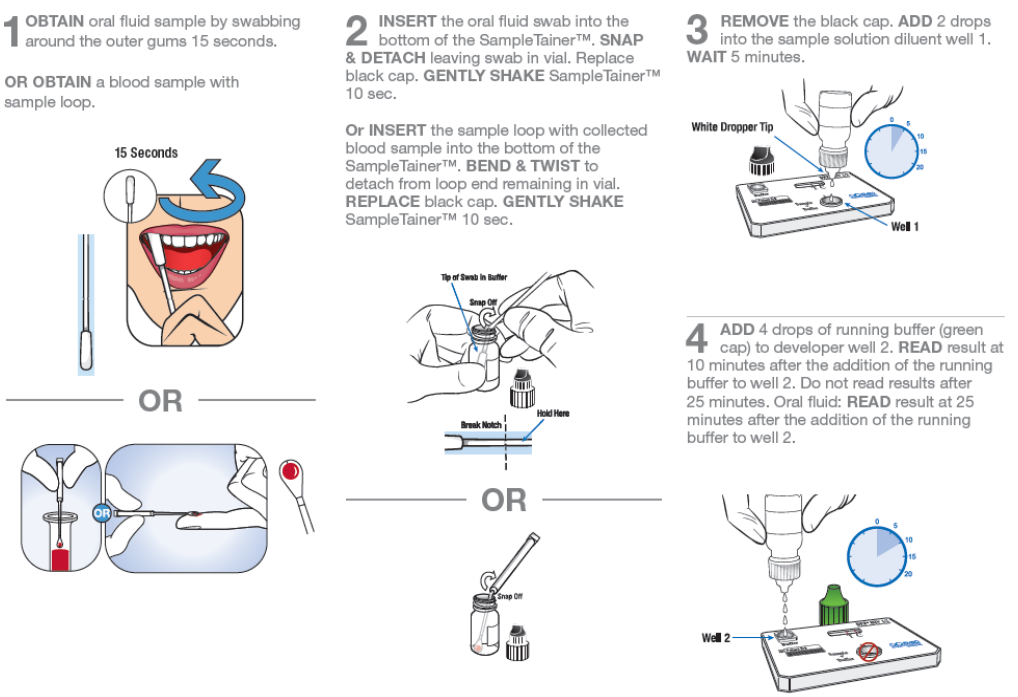
**Sensitivity of the POC DPP HIV 1/2 Assay with Oral Fluid Specimens from Persons with a Previous Diagnosis of HIV Infection**

| | Known HIV-1 infected persons taking antiretroviral medication | | | Known HIV-1 infected persons NOT taking antiretroviral medications | | |
|---|---|---|---|---|---|---|
| Country | n | No. of Positive | Sensitivity, % (95% CI) | n | No. of Positive | Sensitivity, % (95% CI) |
| Nigeria | 129 | 129 | 100 (97.2-100.0) | 86 | 86 | 100 (95.8-100.0) |
| United States | 731 | 723 | 98.9 (97.9-99.5) | 137 | 137 | 100 (97.3-100.0) |
| Total | 860 | 852 | 99.1 (98.2-99.6) | 223 | 223 | 100 (98.4-100.0) |

## Analytical Data Show Detection of Sero-conversion Samples Earlier than all FDA Approved Lateral Flow HIV Tests

# DPP HIV 1/2 Assay –Anticipated U.S. Launch – 2H:13

- Uses Proprietary SampleTainer™ Sample Collection System
- Excellent Performance, Similar Procedure for All Sample Matrices
- CLIA Waiver Studies Pending
- Market Opportunity
  - Become Preferred Oral Fluid HIV Test
  - Demonstrate Earlier Detection Capability on Blood Samples



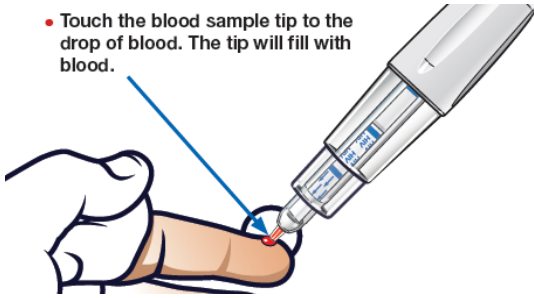
# U.S. Rapid HIV Test Market

- **Estimated $75MM Market**
  - 10% Average Annual Growth
  - ~50,000 New Infections Annually
  - Routine Testing Reimbursed
  - Improved Treatments


- **Market Share Estimates**
  - Orasure - Market leader - 60% share
  - Chembio's Lateral Flow (Alere) - 25% share
  - Trinity & Others -15%
- **Trend Toward "4th Generation" Assays**
  - Chembio Developing "D" DPP®

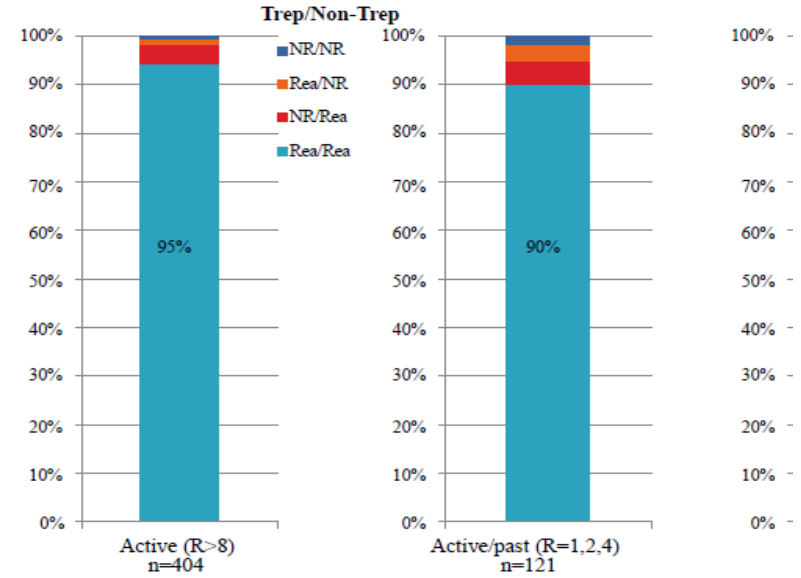
# U.S. HIV Self-Testing "OTC" Opportunity

- Chembio Uniquely Positioned
- Filing IDE Q1 2013 for Sure Check HIV
- Pre-IDE Self-Testing Studies Show 100% Accuracy (n=300)
- Can Also Pursue for DPP® Oral Fluid Test




# Pipeline: DPP® Syphilis Screen & Confirm Test

- First Dual POCT for Syphilis Enables Confirmation & Treatment At POC
- CE Marked
- FDA Meeting Q1 RE: Clinical Pathway
- Clinical Trials and FDA Submission Anticipated 2013
- Anticipated U.S. Market Launch 2014


Trep=Treponemal bar, Non-Trep=non-Treponenal bar; NR=non-reactive, Rea=reactive

**Clinical Sensitivity of 95% for Active Syphilis (RPR>8) and 90% for Active/Past Infection (RPR<4)**

# Pipeline: DPP® HIV-Syphilis Multiplex Test

- High Co-Infection Rates, Particularly in MSM
- Adds Syphilis Test Line to Already FDA-Approved HIV Assay
- Excellent Pre-Clinical Data
- Discussing Regulatory Pathway with FDA-CBER & CDRH Q1 -2013

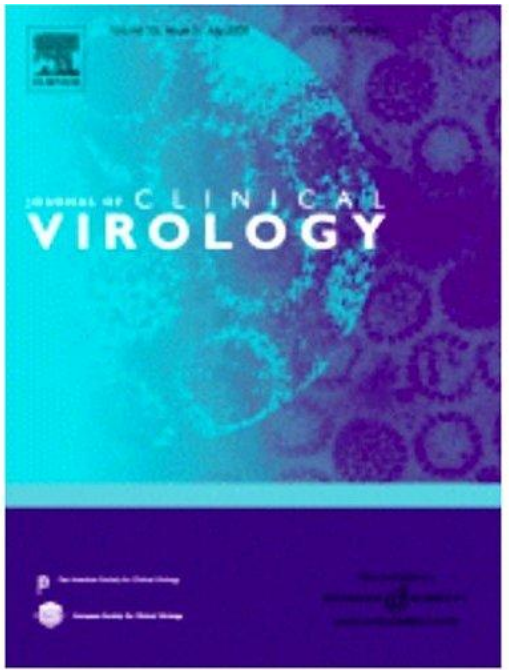

| DPP HIV-Syphilis Line | N | # Pos | Sensitivity | 95% Conf. Interval |
|---|---|---|---|---|
| HIV | 398 | 398 | 100% | 99.1 to 100% |
| Syphilis Trep | 83 | 83 | 100%* | 95.7 to 100% |

*Compared with ELISA followed by RPR Confirmation

| Sample | n | DPP Syphilis Specificity | Syphilis Trep EIA |
|---|---|---|---|
| Blood | 330 | 96.9% (320/330) | Not approved for blood |
| Serum | 202 | 96.5% (195/202) | 96.0% (194/202) |
| Plasma | 407 | 97.3% (396/407) | 94.8% (386/407) |

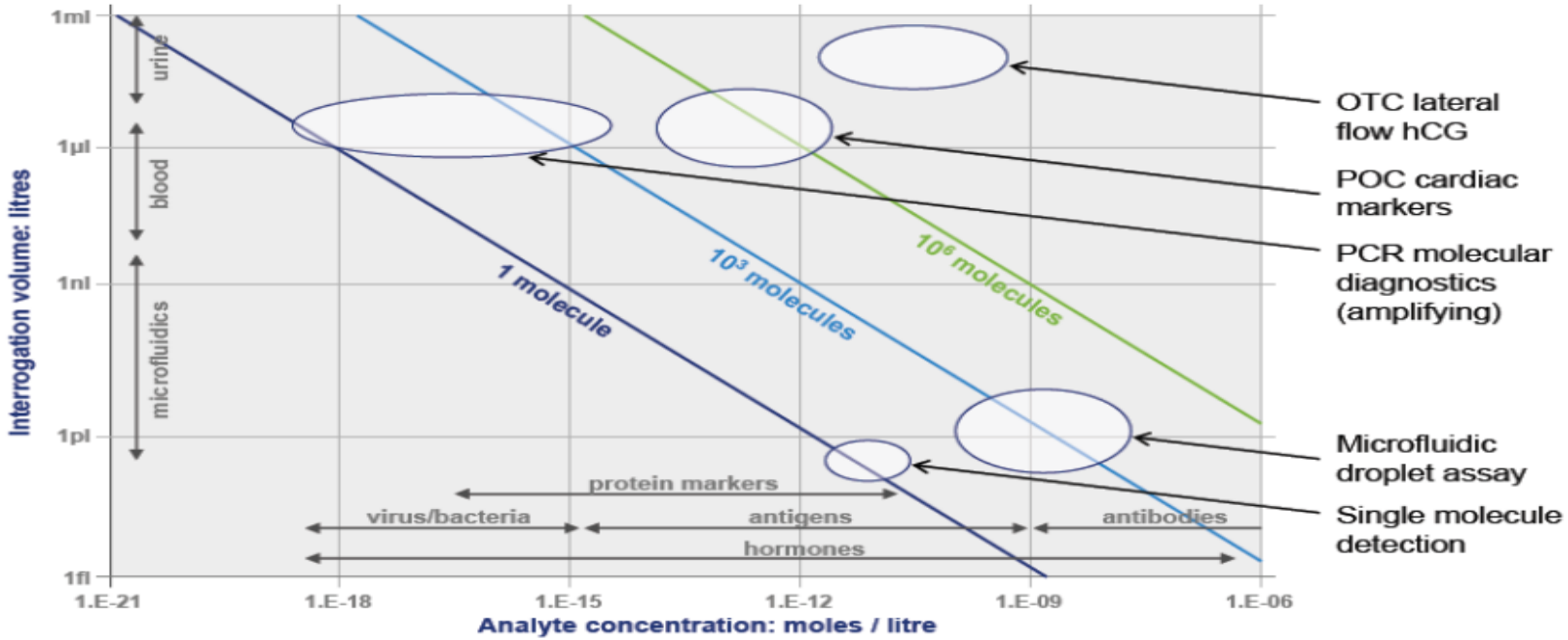
# Pipeline: Rapid Hepatitis C Point-of-Care Diagnostic

- Data Published in *Journal of Clinical Virology* showed good performance of Chembio's 1st Generation Prototype Assay
- Completed Feasibility to Establish Performance Comparable to Only POCT HCV Test – 2013 R&D to incorporate additional value-added features
- Recent CDC recommendations for testing on everyone born between 1945-1964
- Anticipated Timeline
  - Development & Clinical Trials – 2013-2014
  - US Market Launch Anticipated - 2015



# New POCT Markets Will Require Even Lower Levels of Detection

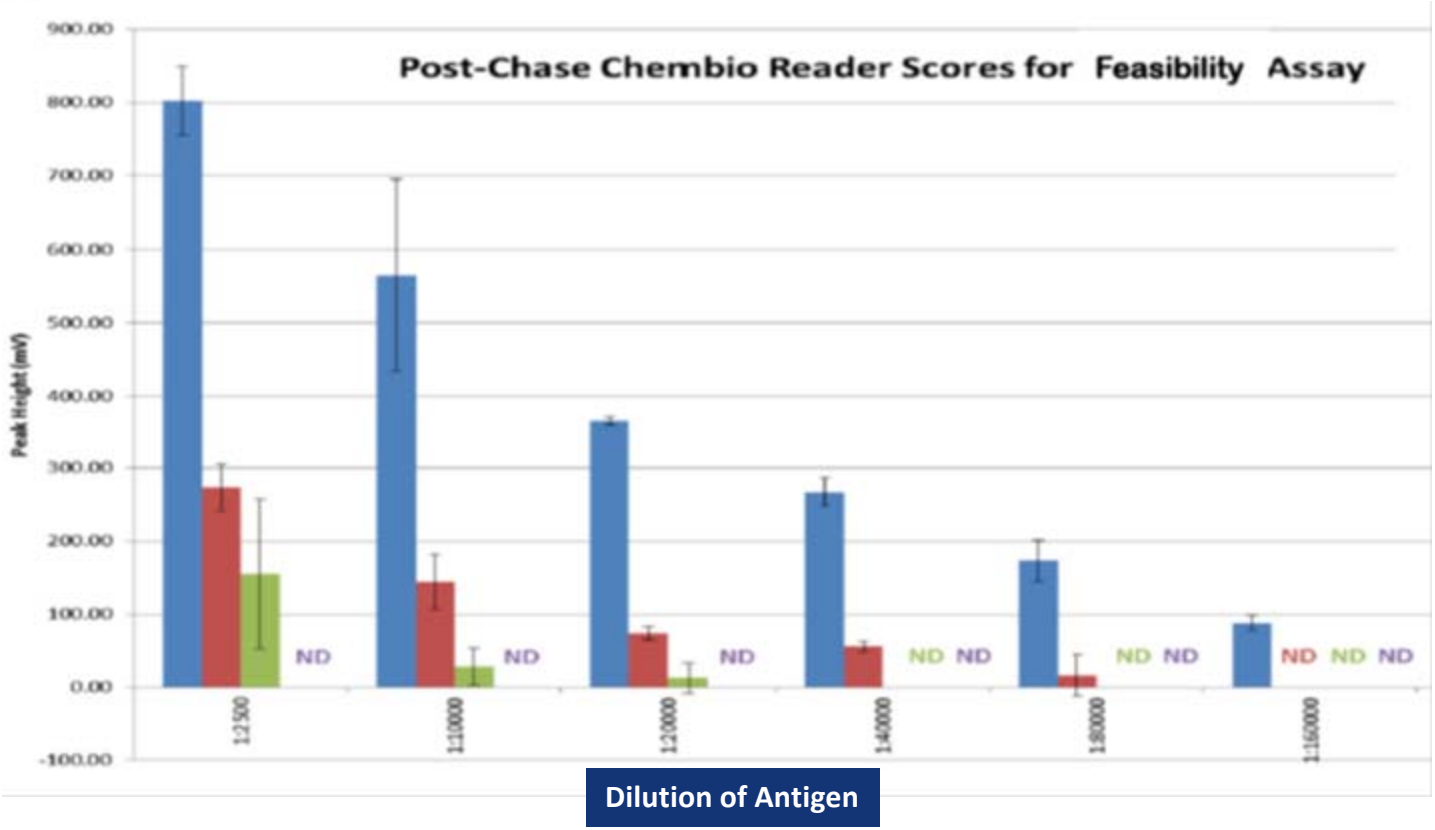
. . . with a challenging trend towards smaller, lower concentration samples




**Potential New POCTs : HIV 4th Gen., HCV, CT-NG, HSV, Maternal Health & Cardiac Markers Assays Incorporating Unique DPP® Features**

CHEMBIO

# Chembio is Investing in Developing the Capabilities to Meet Future POCT Market Requirements



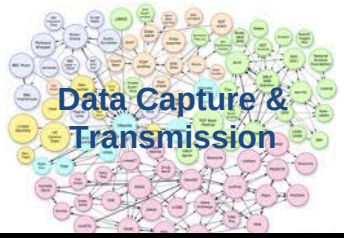

**Incorporating A Selected Detection Technology DPP® Prototype Has Achieved >16-fold Increase In Limit Of Detection For a Virus Analyte**

# Future DPP® POCTs Will Be Connected to Readers to Record and Transmit Results


## Health Workers

## Health Program Managers

Monitoring, Evaluation, & Reporting



Data Capture & Transmission

Health Worker Guidance

**Readers Can Improve Multiplex Test Interpretation Utilizing DPP's High Contrast Test Lines**

CHEMBIO

# Strong Revenue & Operating Income Growth in FY 2012

- **Brazil Revenues Up Significantly vs. 2011**
- **Increased U.S. Sales Through Alere**
- **Large International Orders Received in Q3-4 Shipped in Q4 and anticipate in Q1 2013**
- **Strong Outlook for 2013**

| in (000's) | YTD Sept 30, 2012 | | YTD Sept 30, 2011 | |
|---|---|---|---|---|
| Net Product Revenues | $ 16,919 | | $ 11,516 | |
| Non-Product Revenues | $ 825 | | $ 1,655 | |
| TOTAL REVENUES | $ 17,744 | | $ 13,171 | |
| GROSS MARGIN | $ 7,632 | 43% | $ 6,647 | 50% |
| OPERATING COSTS: | | | | |
| Research and development exp. | $ 3,364 | 19% | $ 3,697 | 28% |
| Selling, general and administrative exp. | $ 3,522 | 20% | $ 2,413 | 18% |
| | $ 6,886 | | $ 6,110 | |
| INCOME FROM OPERATIONS | $ 746 | | $ 537 | |
| OTHER INCOME (EXPENSES): | $ (2) | | $ (9) | |
| NET INCOME-Before Taxes | $ 744 | 4% | $ 528 | 4% |
| Income tax (benefit) provision | $ 295 | | $ - | |
| NET INCOME | $ 449 | 3% | $ 528 | 4% |

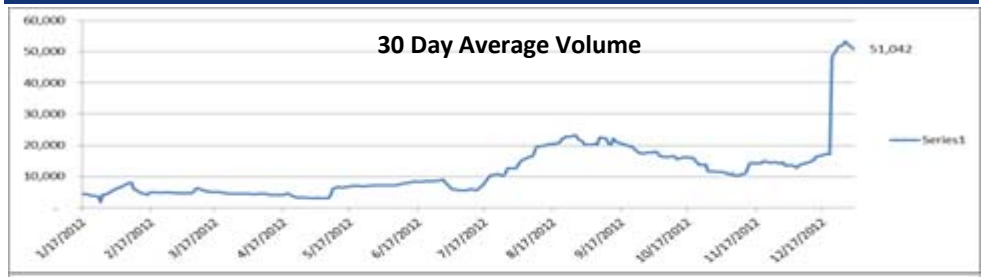
CHEMBIO

# CEMI Selected Share & Balance Sheet Data

| in millions except per share and daily volume data | |
|---|---|
| Ticker Symbol (NASDAQ) | **CEMI** |
| Price 12/31/12 | **$4.73** |
| 52-Week High | **$5.80** |
| 52-Week Low | **$3.10** |
| Outstanding Shares | **8.00** |
| Market Capitalization | **$38.8** |
| Fully Diluted Shares | **8.8** |
| Management Holding | **1.6** |
| Average Daily Volume (3 months) | **52,000** |
| Average Daily Volume (1 month) | **76,500** |

| Options | Amt. | Avg. Ex. Price |
|---|---|---|
| 578K held by Mgmt. & Board | 764K | $2.08 |

| ($ in millions) | Sept'12 | Dec'11 | Dec. '10 |
|---|---|---|---|
| Cash | $ 3,290 | $ 3,011 | $ 2,136 |
| Total Current Assets | 9,601 | 8,992 | 7,637 |
| Total Assets | $16,140 | $ 15,486 | $ 9,086 |
| Total Current Liabilities | 2,761 | 2,858 | 3,076 |
| Total Liabilities | 2,856 | 2,991 | 3,277 |
| Total Equity | 13,284 | 12,495 | 5,809 |
| Total Liabilities & Stockholders' Equity | $16,140 | $ 15,486 | $ 9,086 |



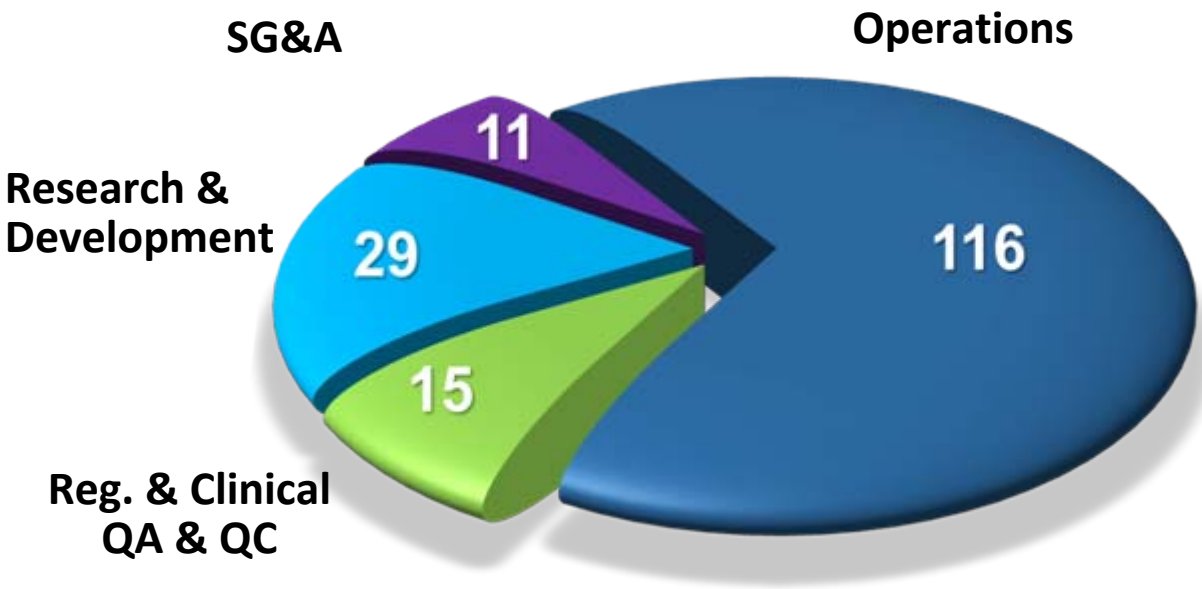

# Leadership

| Executive | | Joined Company |
|---|---|---|
| Lawrence Siebert | Chairman & CEO | 2002 |
| Richard Larkin | CFO | 2003 |
| Javan Esfandiari | SVP Research & Development | 2000 |
| Tom Ippolito | VP Regulatory & Clinical Affairs | 2005 |
| Sharon Klugewicz | VP QA/QC & Technical Operations | 2012 |
| Rick Bruce | VP Operations | 2000 |
| Michael Steele | VP Sales Marketing & Bus. Dev. | 2012 |
| **Independent Directors** | | **Joined Board** |
| Gary Meller, MD, MBA | | 2005 |
| Katherine Davis, MBA | | 2007 |
| Barbara DeBuono, MD, MPH | | 2011 |
| Peter Kissinger, Ph.D | | 2011 |

# Organization & Facility

- *FDA & USDA-Approved Development & Manufacturing Facility*
- *All Company Operations in 28,000 Sq. Ft. Leased Facility in Medford, NY*


**TOTAL EMPLOYMENT**
**Approximately 170**



# Investment Summary

- Develops, Manufactures & Markets Point-of-Care Diagnostic Tests (POCTs) Using Company's Patented DPP® Platform Technology
- Current Revenues Primarily from HIV & Syphilis POCTs Sold Globally
- Profitable FY2009-2011 & 9 Months of 2012
  - Anticipate Strong Fourth Quarter 2012 Sales
- Partnered with Leading License & Distribution Partners in U.S. & South America
- Recent FDA Approval of Oral Fluid HIV Test
  - First DPP® test approved by FDA
- Strong Pipeline of POCTs
- Experienced Management Team

CHEMBIO DIAGNOSTICS, INC.

# THANK YOU


## RAPID tests for EARLIER treatments

**Investor Presentation** **NASDAQ: CEMI** **January 2013**